

## **REMARKS**

### **I. Status of the Application**

Claims 1 – 11 and 13 – 22 are pending in the application. Claims 1, 4, 7 – 9, 11, 15, 20, and 21 stand rejected under 35 U.S.C. §102(b) as being anticipated by Japanese Patent No. 07099965 A.

Applicants have amended the claims to more clearly define and distinctly characterize Applicants' novel invention and to place the claims into condition for allowance. Claims 1, 4, 8, 9, and 11 have been amended to recite a number average degree of polymerization of at least 7. Support for the amendment to claims 1, 4, 8, 9, and 11 can be found at least at page 5 lines 20 – 25 where a preferred embodiment of the claimed invention having a number average degree of polymerization of at least 7 is disclosed. Further support for the claimed degree of polymerization is found in Table I, which shows a direct correlation between increasing  $DP_n$  and improved stability of alkaline phosphatase. For example, a  $DP_n$  for inulin of 5.5 resulted in no activity of alkaline phosphatase after 6 days, whereas increasing the  $DP_n$  led to a marked increase of alkaline phosphatase activity over the same 6-day period.

Applicants respectfully request entry and consideration of the foregoing amendments, which are intended to place this case in condition for allowance.

### **II. Claims 1, 4, 7 – 9, 11, 15, 20, and 21 Are Not Anticipated by JP 07099965 A**

At page 2, paragraph 3 of the present Office Action, claims 1, 4, 7 – 9, 11, 15, 20, and 21 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Japanese Patent No. JP 07099965 A (JP 07099965). The Examiner asserts that the JP 07099965 patent teaches a fructan

wherein the degree of polymerization can be 6 and that it would inherently provide a sugar glass form. Applicants respectfully traverse this rejection.

Applicants' claims as amended are directed to a pharmacon incorporated into a fructan having a number-average degree of polymerization of at least 7 in the form of a sugar glass. As discussed above, Table I shows that increasing the number-average degree of polymerization of a fructan sugar glass above 5.5 has a marked effect in stabilizing alkaline phosphatase activity. In contrast, JP 07099965 teaches a  $DP_n$  of between 3 to 6 and fails to teach a  $DP_n$  of at least 7 or any correlation between increasing  $DP_n$  and increasing stabilization. See JP 07099965, at 1 (a "protector for microbes or cells contg. inulin type fructan as the active component, the degree of polymerization of the inulin type fructan being pref. 3-6.").

Further JP 07099965 includes no explicit teaching that its inulin type fructan is in a sugar glass state. Instead, the Examiner is relying on an inherency argument. However, for the Examiner to succeed on his inherency argument, the fructan of JP 07099965 must necessarily be in the sugar glass state. Applicant's own specification, however, at least at page 9, line 28 – page 10, line 5, teaches that freeze drying does not necessarily produce a fructan in a sugar glass state. In fact, applicants teach that freeze-drying may fail to produce a fructan in a sugar glass state because it is cooled too slowly or sublimation may take place at a temperature higher than the glass transition temperature. If either of these conditions is present, no sugar glass will form. It is not clear, nor is there a reasonable basis to assume from JP 07099965 that a sugar glass is formed, and therefore, it cannot be assumed that JP 07099965 inherently teaches a sugar glass.

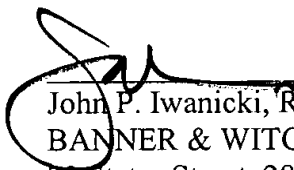
Thus, JP 07099965 fails to teach all of Applicants' claim limitations. Accordingly, Applicants respectfully request that the rejection of claims 1, 4, 7 – 9, 11, 15, 20, and 21 under 35 U.S.C. § 102(b) be withdrawn.

### III. Conclusion

Reconsideration and allowance of all the pending claims is respectfully requested. If a telephone conversation with Applicants' attorney would expedite prosecution of the above-identified application, the Examiner is urged to call the undersigned at (617) 720-9600.

Respectfully submitted,

Dated: November 3, 2003



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